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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09X049,227 03/27/98 REDMON M 4821-304

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EXAMINER

DELACROIX MUIRHEI, C

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

11/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/049,227

Applicant(s)

REDMON et al.

Examiner

Delacroix-Muirhead

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on Mar. 23, 2000 and Sep. 2, 1999.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-38 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-38 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11
- ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

The following is responsive to the amendment received March 23, 2000 and the Information Disclosure Statement (IDS) received Sep. 2, 1999.

In view of art submitted in the IDS as well as art found in an update search, the finality of the office action mailed Sep. 23, 1999 is withdrawn and a new ground of rejection is submitted hereinbelow.

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Sep. 2, 1999 has been considered. Please refer to a copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

1. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Claim 22 recites the limitation "the solid pharmaceutical composition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 21, 29 and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by El-Rashidy et al., 5,830,500.

El-Rashidy et al. disclose the invention substantially as claimed. Specifically, El-Rashidy et al. teach a compressed tablet comprising racemic fluoxetine hydrochloride, a lubricant and a disintegrant such as microcrystalline cellulose or pregelatinized starches. A preferred compressed tablet formulation is described in TABLE 1. Please see col. 2, lines 8-9 and lines 52-55; col. 3, lines 37-43; TABLE 1.

Claim 23 is anticipated by El-Rashidy because El-Rashidy discloses a similar solid pharmaceutical composition comprising racemic fluoxetine hydrochloride and pharmaceutically acceptable excipients such as microcrystalline cellulose and pregelatinized starches. Accordingly, the El-Rashidy compositions would be inherently anhydrous.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
- section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
- such that the subject matter as a whole would have been obvious at the time the invention was made to a person
- having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the
- manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

• This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al., supra in view of the Physicians Desk Reference (PDR), 50th edition (1996).and WO 97/31629 ('629).

• In addition to the teachings described above, El-Rashidy et al. further disclose that the compositions are made from dry ingredients and formed into tablets by direct compression method. Please see col. 3, lines 64-66. Moreover, while the claimed tablets dissolve in less than

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three minutes, El-Rashidy does disclose that commercially known fluoxetine compositions dissolve in 4 minutes 36 seconds. See col. 5, lines 61-64.

El-Rashidy et al. do not disclose pharmaceutical compositions containing an optically pure enantiomer of fluoxetine; however, the Examiner refers to the teaching in PDR, page 919, under CLINICAL PHARMACOLOGY, Enantiomers, wherein it is stated that both the R- and S- enantiomers of fluoxetine are specific and potent serotonin uptake inhibitors.

It would have been obvious to one of ordinary skill in the art to modify the pharmaceutical compositions of El-Rashidy et al. to contain optically pure enantiomers of fluoxetine because PDR further discloses that the R- and S- enantiomers of fluoxetine have essentially equivalent pharmacologic activity. Thus, such a modification would have been motivated by the reasoned expectation of successfully producing an equally effective pharmaceutical product.

Concerning the claimed dissolution times of not less than three minutes, it is submitted that in view of El-Rashidy's disclosure, dissolution time is an art-recognized result-effective variable and it would have been obvious and well within the capability of the skilled artisan to optimize it the compositions of El-Rashidy. The Examiner additionally relies on WO '629 which discloses that dissolution time is one of several known physical characteristics of a tablet (page 3, last three lines). The harder a tablet is the more time it takes to dissolve (page 4, first full paragraph).

Absent evidence to the contrary, it would be obvious to one of ordinary skill in the art to modify the components of a composition until a desired dissolution time, i.e. "not less than three minutes", is acquired. For example, the lack of a disintegrant would obviously result in a composition that does not dissolve as quickly as it would with a disintegrant.

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With respect to the claimed compositions being anhydrous or nonhygroscopic or substantially free of unbound water, the Examiner submits that this is obvious in view of El-Rashidy's teaching that the compressed tablets are made from dry ingredients.

Finally, in addressing claims 14, 17 and 18, which require a specific amounts of fluoxetine and excipient, concentration limitations are obvious absent evidence to the contrary. Please see Akzo v. E.I. du Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987).

8. Claims 1, 2, 13, 14, 21, 23, 24, 30, 33, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al. in view of EPA 0693281 ('281).

El-Rashidy et al. as applied above.

El-Rashidy et al. do not disclose using the fluoxetine compositions to treat depression. Yet, for this feature, the Examiner refers to EPA '281 which discloses pharmaceutical compositions for treating depression, wherein said compositions contain fluoxetine or an acid addition salt thereof suitable for manufacturing dispersible tablets by direct compression and further comprise appropriate excipients and coadjuvants. Some of the preferred compositions in EPA '281 **do not contain any lactose**. Please refer to the abstract; page 3, line 28 to page 4, line 28; page 5, line 22-31; Examples 2-20.

It would have been obvious to one of ordinary skill in the art to use the fluoxetine compositions of El-Rashidy to treat depression because EPA '281 discloses that fluoxetine is a known antidepressant useful in treating depression (see page 2, lines 10-16). Thus, the use of the compositions disclosed by El-Rashidy in a method for treating depression would have been

motivated by the reasoned expectation that the fluoxetine compositions would be useful in treating individuals suffering from depression.

Claim Rejections - 35 USC § 112

9. Claims 13-20, 22, 29, 35, 37, 30-32, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations, (1) "wherein said tablet does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST" and (2) "said tablet dissolves in more than five minutes when subjected to the DISSOLUTION TEST" render the claims vague and indefinite because it is not clear whether the conditions required for the DISSOLUTION TEST in the specification at page 18 remain constant or if they may change over a period of time. The scope of the claims remains uncertain because if the conditions of the test change then the scope of the claims change as well.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson et al., 5,985,322, see col. 3, lines 17-22.

Claims 1-38 are rejected.

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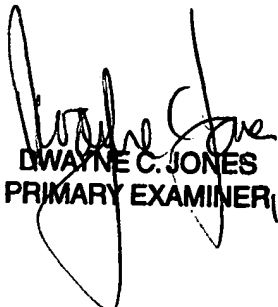
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM 
Oct. 24, 2000


DWAYNE C. JONES
PRIMARY EXAMINER 1614